

# In The United States Court of Federal Claims

No. 10-704 V

(Filed Under Seal: April 11, 2016)

Reissued: April 26, 2016<sup>1</sup>

KIMBERLY FAORO and TYSON  
FAORO, as Parents and Natural Guardians  
of H.E.F.

Petitioners,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

\*  
\* Entitlement; SCN1A Gene Mutation; Severe  
\* Myoclonic Epilepsy of Infancy (“SMEI”);  
\* Dravet Syndrome; Seizure Disorder;  
\* Diphtheria Tetanus acellular Pertussis  
\* (“DTaP”) Vaccine; Haemophilus Influenza  
\* Type B (“HiB”) Vaccine; Pneumococcal  
\* Conjugate Vaccine (“Prevnar”); Rotavirus  
\* Vaccine; Significant Aggravation;  
\* Alternative Causation.  
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## OPINION

*Martin A. Diaz*, Diaz Law Firm, Iowa City, IA, for petitioners.

*Jennifer Leigh Raynaud*, United States Department of Justice, Washington, DC, for respondent.

### SMITH, Senior Judge:

Petitioners, Kimberly Faoro and Tyson Faoro, as parents and natural guardians of their daughter, H.E.F., seek review of a decision issued by Chief Special Master Nora Beth Dorsey denying their petition for vaccine injury compensation. Petitioners brought this action pursuant to the National Vaccine Injury Compensation Act, 42 U.S.C. §§ 300aa-10 et seq. (2012), alleging that H.E.F. developed seizures, brain damage, and developmental delay as a result of the

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<sup>1</sup> An unredacted version of this opinion was issued under seal on April 11, 2016. The parties were given an opportunity to propose redactions, but no such proposals were made. Nevertheless, the court has incorporated some minor changes into this opinion.

diphtheria-tetanus-acellular-pertussis (“DTaP”) vaccine, hepatitis-B (“Hep B”) vaccine, inactive polio vaccine (“IPV”), and haemophilus influenza type b (“Hib”) vaccine, which she received at her four month well-child visit. In the alternative, petitioners posit that those vaccines “significantly aggravated ...an underlying genetic pre-disposition.” Petition (“Pet”) at 1, 7. The Chief Special Master denied compensation, finding that H.E.F.’s Dravet syndrome was not caused or significantly aggravated by the vaccinations. *Faoro v. Sec’y of Health & Human Servs.*, 2016 WL 675491 (Fed. Cl. Jan. 29, 2016) (“*Faoro*”). Petitioners now move for review of this decision. For the reasons that follow, the court **DENIES** their motion.

## I. BACKGROUND

A brief recitation of the facts, as presented by the Chief Special Master follows:

### A. Factual History

H.E.F. was born on August 28, 2007. She was delivered at 40 weeks gestation. Her newborn screening tests were all normal. H.E.F.’s mother (“Ms. Faoro”) was 27 when H.E.F. was born, and H.E.F. was her fifth child.

H.E.F. was often sick during her first few months. On September 4, 2007, she was treated for diarrhea and diaper rash. She was treated for a mild upper respiratory infection on September 11, 2007. On October 2, 2007, she was seen and treated for thrush and dermatitis.

On October 22, 2007, H.E.F. received her two month vaccines—Pediarix<sup>2</sup>, Hib, Prenevar,<sup>3</sup> and RotaTeq.<sup>4</sup> The next day, October 23, 2007, she had a fever of 102 degrees, with vomiting and poor appetite. She was taken to the Emergency Department (“ED”) at the Mahaska Hospital in Oskaloosa, Iowa, where she was seen by Dr. White and was diagnosed with “vomiting and fever status post immunization.” Approximately a week later she was taken to the ED again for fever and diarrhea, where she was diagnosed with an ear infection. On November 6, 2007, she was diagnosed with gastroenteritis and an upper respiratory infection.

On December 28, 2007, H.E.F. attended her four-month well-child visit with Dr. White, at which time she received her four-month vaccines—Pediarix, Hib, Prenevar, and RotaTeq. Approximately six to seven hours after receiving her vaccines, H.E.F. began to have “shaking of her right side involving both her arm and leg” and temporarily lost the use of her right arm. Petitioners’ Exhibit (“Pet. Ex”) 7 at 92. She went to the ED, where examination revealed her

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<sup>2</sup> Pediatix is the “trademark for a combination preparation of hepatitis B vaccine (recombinant), diphtheria and tetanus toxoids and acellular pertussis (“DTaP”) vaccine, and poliovirus vaccine inactivated.” *Dorland’s Illustrated Medical Dictionary* 1400 (32 ed. 2012) (“*Dorland’s*”).

<sup>3</sup> Prevnar is the “trademark for a preparation of pneumococcal 7-valent conjugate vaccine.” *Dorland’s* at 1514.

<sup>4</sup> RotaTeq is the “trademark for a preparation of rotavirus vaccine, live, oral, pentavalent.” *Dorland’s* at 1655.

temperature at 99.4 degrees and decreased strength and tone of her right arm. Her CT scan results were all normal, and Dr. White diagnosed H.E.F. with “seizure most likely [secondary] to DTaP vaccine.” *Id.* at 95. H.E.F. was then sent home at 9:30 p.m., but she returned to the ED around 2:00 a.m. on December 29, 2007, after a second episode of seizure activity, which resulted in H.E.F.’s left arm and leg remaining flaccid for 2 hours after said seizure activity. Her temperature was 99.5 degrees. She was transferred to the Blank Children’s Hospital (“BCH”) in Des Moines, Iowa, for further treatment. At BCH, Dr. Duangchai Narawong diagnosed H.E.F. with complex febrile seizures and gave her phenobarbital and Diastat before discharging her home on December 30, 2007.

H.E.F.’s next seizure was on January 17, 2008, and was associated with a respiratory syncytial virus (“RSV”). H.E.F. was taken to the ED at Mahaska Hospital, after Emergency Medical Service (“EMS”) was called because she was experiencing “involuntary muscle tremors and jerking in her left-side extremities” after which her left upper extremity was immobile. Pet. Ex. 7 at 141. Her temperature was 101 degrees. During the admission process at Mahaska Hospital, H.E.F. experienced another seizure, which included “twitching of the right side which affected both the arms and legs.” *Id.* at 115. Her temperature following the second seizure was 103 degrees, and she was airlifted to BCH.

H.E.F. experienced two more seizures on February 6, 2008. She was given phenobarbital, valium, and Tylenol. Despite the seizures, the remainder of her physical exam “was within normal limits except for plaque on the tongue and buccal musosa.” Pet. Ex. 7 at 159. H.E.F. did not have another seizure until April 8, 2008, when she was taken to Mahaska Hospital by ambulance because of generalized twitching of her left extremities for 45-50 minutes. Her fever was 102 degrees. She was airlifted to BCH, where she was intubated due to hypoxemia. Dr. Narawong again diagnosed her with complex febrile seizures. H.E.F. was admitted to Mercy Medical Center in Des Moines, Iowa from May 10-12, 2008, for increased seizure activity.

On June 12, 2008, H.E.F. was referred to the Mayo Clinic for repeated episodes of “status epilepticus,” at which point she was diagnosed with “epilepsy with tendency for recurrent prolonged seizures.” Pet. Ex. 16 at 7, 9. She continued to have seizures, and on July 23, 2008, Dr. K.C. Nickels diagnosed H.E.F. with intractable recurrent seizures and noted that she may have Dravet syndrome. She continued to have seizures throughout 2009-2010, associated with fevers of 104 and 105 degrees. In June of 2012, during a visit to the Mayo Clinic, Dr. Amy M. Martyanov noted that although she was doing well regarding her seizure control, H.E.F. “has very classic Dravet’s phenotype with prolonged seizures that are temperature sensitive.” *Id.* at 57.

## **B. SCN1A Mutation, Dravet Syndrome, and Developmental Delay**

H.E.F. underwent genetic testing at the Mayo Clinic on June 12, 2008. The results were reported by Transgenomic Clinical Reference Laboratory on September 5, 2008, and the results revealed that H.E.F. has a novel SCN1A mutation. Essentially, this mutation impacts a cell’s ability to generate and transmit electrical signals; it also stops the translation of cell proteins before they are complete. Medical literature has referred to similar SCN1A mutations as

truncation mutations in the SCN1A gene. Because H.E.F.'s mutation is novel, it has not been previously reported as being associated with Dravet syndrome or other severe forms of epilepsy. However, similar SCN1A mutations have almost always been shown to be disease causing.

H.E.F.'s parents underwent genetic testing to determine if they have the same SCN1A mutation. Only H.E.F.'s mother tested positive for the mutation, but she is entirely asymptomatic. To explain this, respondent put forth the theory of mosaicism<sup>5</sup>, which means that the mutation is only in some of Ms. Faoro's cells. Mosaicism would allow Ms. Faoro to pass the mutation to some, but not all of her children, and, depending on the frequency of her mutated cells, explains why Ms. Faoro is asymptomatic.

Dravet syndrome is a rare condition. Seventy to eighty percent of Dravet syndrome cases are caused by SCN1A mutations.<sup>6</sup> Essentially, Dravet syndrome affects the Na<sub>v</sub>1.1 sodium channel, which functions to maintain a neurological balance in the brain. If this channel dysfunctions, it can lead to seizures.<sup>7</sup> Dravet syndrome is also referred to as Severe Myoclonic Epilepsy of Infancy ("SMEI") and it typically begins around six months of age.<sup>8</sup> Initial seizures can be accompanied by fever. While development is typically normal at the onset of the disease, there is subsequent and progressive decline in intellectual function. The typical time frame for the disease's onset often "overlaps" with routine childhood vaccinations. Children with Dravet syndrome typically have clonic<sup>9</sup> seizures during their first year of life, followed myoclonic<sup>10</sup> seizures. Children with Dravet syndrome also can have ataxic<sup>11</sup> gait.<sup>12</sup> The seizures are refractory to treatment.

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<sup>5</sup> Mosaicism is described as "in genetics, the presence of an individual of two or more cell lines that are karyotypically or genotypically distinct and are derived from a single zygote." *Dorland's* at 1181.

<sup>6</sup> Respondent's Exhibit ("Res. Ex.") C-29, Marini C et al., *SCN1A duplications and deletions detected in Dravet Syndrome: implications for molecular diagnosis*, 50(7) *Epilepsia* 1670-78, 1671 (2009).

<sup>7</sup> Res. Ex. C-9, Oakley JC et al., Temperature- and age-dependent seizures in a mouse model of severe myoclonic epilepsy in infancy, 106(10) *Proc. Nat'l Acad. Sci. USA* 3994-99 (2009).

<sup>8</sup> Pet. Ex. 30-V, Tro-Baumann et al., "A retrospective study of the relations between vaccination and occurrence of seizures in Dravet syndrome," 52(1) *Epilepsia* 175, 175 (2011).

<sup>9</sup> Clonic is an adjective of the word "clonus" which is defined as "alternate muscular contraction and relaxation in rapid succession." *Dorland's* at 373.

<sup>10</sup> Myoclonic seizures are characterized by "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously or asynchronously in several areas." *Dorland's* at 1222.

<sup>11</sup> Ataxia is the "failure of muscular coordination; irregularity of muscular action." *Dorland's* at 170.

<sup>12</sup> Res. Ex. C-2, Guerrini et al., Borderline Dravet syndrome: A useful diagnostic category?, 52(2) *Epilepsia* 10, 10 (2011).

H.E.F.'s development was consistent with that of other children with Dravet syndrome. Her development was overwhelmingly described as normal throughout her first year of life, despite the recurrent seizures and numerous illnesses. However, on January 9, 2009, when H.E.F. was 16 months old, Dr. Nickels noted that H.E.F. did not have a pincer grasp, which is a nine-month old milestone. On January 16, 2009, H.E.F.'s development was described as slow and at the nine or ten month old development stage. On July 27, 2009, Dr. Nickels noted that H.E.F. did not say any "recognizable words." Pet. Ex. 16 at 97. When H.E.F. was diagnosed with Dravet syndrome on July 11, 2013 (at almost six years of age), she was noted to have "developmental delay, ataxia, dysmetria, and behavioral control consistent with Dravet syndrome comorbidities." Pet. Ex. 16b at 5-6.

### **C. Procedural History**

Petitioners filed their vaccine petition on October 15, 2010, pursuant to the Vaccine Act. Respondent filed her report pursuant to Vaccine Rule 4(c) on March 28, 2011. Petitioners filed four expert reports from Dr. Barbara Burton<sup>13</sup> and one expert report from Dr. Marcel Kinsbourne.<sup>14</sup> Respondent filed two expert reports from Dr. Rajesh Sachdeo<sup>15</sup> and two expert

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<sup>13</sup> Dr. Burton is a medical geneticist who currently practices at the Ann & Robert H. Lurie Children's Hospital of Chicago (affiliated with Northwestern University School of Medicine). Transcript of Proceedings, June 3-4, 2014, page 47 (hereinafter "Tr. \_\_\_\_"). She attended medical school at Northwestern University Feinberg School of Medicine, and completed her residence in pediatrics, followed by a two-year fellowship in medical genetics at Children's Memorial Hospital. She is board-certified by the American Board of Pediatrics and the American Board of Medical Genetics, with subspecialties in clinical genetics and clinical biochemical genetics. She is currently a Professor of Pediatrics at Northwestern University, a member of the Center for Genetic Medicine, and a Clinical Practice Director of the Division of Genetics at Children's Memorial Hospital. While she occasionally sees patients with Dravet syndrome for genetic counselling, evaluation, and diagnosis, she does not typically provide ongoing care or treatment. Tr. 49.

<sup>14</sup> Dr. Kinsbourne is currently a tenured professor of clinical psychology for graduate students at the New School, University of New York. Tr. 120. He received his medical degree from Oxford University in 1955. Tr. 122. After receiving his medical degree, he studied neurology, general pediatrics, and pediatric neurology until 1964. Pet. Ex. 31A at 1-2. He then came to the United States and was a professor at a number of schools from 1967 through 1995, at which time he assumed his current position. He has not seen patients in significant numbers since 1981. Tr. 126. He considers himself a pediatric neurologist with a special interest in behavioral disorders, including autism. Tr. 127. He concedes that he is not a geneticist, but asserts that he is conversant in neurogenetics to the extent that he can "understand the findings, evaluate them, and apply them to patient care." Tr. 128.

<sup>15</sup> Dr. Sachdeo is a neurologist specializing in epilepsy and treating children and adults with seizure disorder. Tr. 208. He attended the Christian Medical College in India before moving to the United States and completing his residency at Loyola University Medical Center. He obtained a subspecialty in epilepsy through a fellowship at Rush-Presbyterian Medical College in Chicago. Res. Ex. A-6 at 2. He is currently a Clinical Professor of Neurology at

reports from Dr. Gerald Raymond.<sup>16</sup> In total, the parties filed 72 medical texts and article, and both parties filed pre-hearing briefs.

A two-day hearing was held on June 3-4, 2014. A post-hearing status conference was held on June 26, 2014, to discuss the issue of having Ms. Faoro's other biological children tested for the SCN1A gene mutation. The testing took 10 months to complete, and the results were returned on May 20, 2015, indicating that Ms. Faoro's other six biological children tested "negative for the specific mutation tested." Pet. Ex. 43. Both parties were given the opportunity to file supplemental expert reports to address the significance of the genetic testing. *See* Order dated May 26, 2015. The parties filed a joint status report on July 10, 2015, declining the opportunity to file supplemental reports. On July 13, 2015, the record was confirmed as completed for the purposes of determining entitlement.

Then, on August 3, 2015, respondent filed a motion for leave to file a supplemental report from Dr. Raymond and additional literature on the basis that respondent had additional relevant evidence. The motion indicated that Dr. Raymond had learned of an SCN1A mutation database hosted by the Institute of Neurosciences, Guangzhou Medical University, in China. This database had additional medical literature regarding the SCN1A mutation at issue. Respondent's Motion to File Additional Evidence, Aug. 3, 2015, at 1. Petitioners objected that this request was untimely and that it would allow respondent to introduce additional argument about the evidence which the court had not solicited. Petitioner's Response to Motion to File Additional Evidence, Aug. 3, 2015, at 1.

A status conference was held on August 12, 2015, to discuss the dispute. Respondent argued that the database was new information, and that one of the articles identified by the previous motion was a study conducted by the Mayo Clinic involving H.E.F. This article classified H.E.F.'s specific genetic mutation as disease causing. The parties agreed to redact the portions of Dr. Raymond's supplemental report that petitioners considered argument, and they

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UMDNJ Robert Wood Johnson Medical School in New Jersey. Res. Ex. A at 1. He is an attending physician at a number of hospitals and is board-certified in neurology and neurophysiology. *Id.* He has conducted more than 50 studies on epilepsy, authored book chapters and articles on the same, and has an active clinical practice caring for children who have epilepsy. Over the course of his career, he has seen and treated approximately 40-50 patients with Dravet syndrome. Tr. 201. He currently follows 12 to 14 patients with Dravet syndrome. *Id.* He has an active medical license in good standing in New Jersey. Res. Ex. A-6 at 3.

<sup>16</sup> Dr. Raymond is a pediatric neurologist who specializes in neuropathy and genetics. He attended medical school at the University of Connecticut, after which he completed a residency in pediatrics and neurology. Res. Ex. F at 1. He completed a fellowship in developmental neuropathy, genetics, and teratology. *Id.* He is board-certified in pediatrics, clinical genetics, and neurology, with a special competency in child neurology. *Id.* at 10. He has served as a peer reviewer and has published numerous articles in neurology, pediatrics, and genetics. *Id.* at 2-9.

agreed to file the supplemental report and medical literature. The report was filed on August 13, 2015, along with two additional medical articles.<sup>17</sup>

Chief Special Master Dorsey's decision denying entitlement was published on January 29, 2016. On February 23, 2016, petitioners filed a Motion for Review ("MFR") of the Chief Special Master's decision. Respondent filed a Response to petitioners' Motion for Review ("Resp. to MFR") on March 24, 2016. Argument on this motion is deemed unnecessary, and the Motion for Review is now ripe for decision.

## II. DISCUSSION

Under the Vaccine Act, this court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the court may: "(A) uphold the findings of fact and conclusions of law . . . ; (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or; (C) remand the petition to the special master for further action in accordance with the court's direction." *Id.* at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec'y of Health & Human Services*, 92 Fed. Cl. 1, 5 (2010).

*Althen* provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. *See generally, Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). In order to prove causation-in-fact, petitioners must

show by preponderant evidence that the vaccination brought about [his] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Althen*, 418 F.3d at 1278. In order to succeed, petitioners must provide a "reputable medical or scientific explanation" for their claim. *Id.*

Within this framework, petitioners make two numbered objections to the January 29, 2016 Decision. First, they assert that Chief Special Master Dorsey conflated the petitioners' causation theory with the government's causation theory and, in the process, unfairly discounted the reasonableness of the petitioners' theory under the *Althen* test. They purport that this resulted in a higher burden of proof. Second, petitioners contend that the Chief Special Master used the wrong basis for Prong one of the *Loving v. Sec'y of Health & Human Servs.* analysis and, in the process, increased the burden of proof for petitioners. 86 Fed. Cl. 135 (2009). This court

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<sup>17</sup> Chief Special Master Dorsey indicated that the outcome of this decision would have been the same even if Dr. Raymond's supplemental report and additional evidence had not been considered.

disagrees with petitioners' objections, and, for the forgoing reasons, petitioners' motion for review is denied.

#### **A. The *Althen* Test**

Petitioners argue that Chief Special Master Dorsey increased their burden of proof with regard to *Althen* prong one. In support of their theory that the vaccines triggered H.E.F.'s Dravet syndrome, petitioners attempt to use the government's concession that that a vaccine can trigger an earlier onset of Dravet syndrome. Petitioners' Memorandum in Support of Motion for Review MFR ("Mem. Supp. MFR") at 12. Petitioners argue that, because it's possible that the vaccines triggered H.E.F.'s first seizure, there is a "logical sequence of cause and effect showing that the vaccination was the reason for [H.E.F.'s] injury." *Id.* (quoting *Althen*, 418 F.3d at 1278). This conclusion does not consider other factors related to H.E.F.'s seizure disorder, specifically, her SCN1A mutation.

The Chief Special Master assessed the evidence and testimony submitted by both parties and found respondent's theory of causation more persuasive. Petitioners' causal theory is premised upon the "second hit" theory described by Dr. Kinsbourne. Essentially, H.E.F.'s SCN1A mutation may have created a susceptibility towards Dravet syndrome, but H.E.F.'s seizure disorder would not have been triggered but for a "'second hit' in the gene environment interaction." Dec. at 14. Here, the vaccine is the proffered "second hit" which triggered the seizures. *Id.* Respondent conceded that vaccines are linked to fever, fever is linked to seizures, and thus, vaccines could potentially trigger the onset of a seizure in a child with Dravet syndrome. However, Chief Special Master Dorsey determined that the current medical literature supports the finding that vaccines do not affect the prognosis or severity of Dravet syndrome. Dec. at 22. Dravet syndrome will develop regardless of vaccination in children with SCN1A mutations, and truncating mutations, such as the mutation identified in H.E.F., are causally linked to more severe Dravet syndrome prognoses. *Id.*

In order for a petitioner to succeed in a vaccine claim for entitlement, the Vaccine Act requires that "there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. § 300aa-13(a)(1)(B). Essentially, respondent must show that some other factor, unrelated to vaccination, is the "sole substantial factor" causing the alleged injury. *See De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008). Respondent asserts that the SCN1A mutation is the unrelated "sole substantial factor" causally connected to H.E.F.'s Dravet syndrome.

Here, petitioners attempt to argue that it is impossible for respondent to meet its burden under the sole substantial cause theory once petitioners have established a causal theory of their own. Mem. Supp. MFR at 14. Petitioners then proceed to posit that, if respondent cannot meet its burden with an alternative sole substantial cause, petitioners need only put forth "a reasonable theory that can potentially establish a causal link" in order to succeed in their entitlement claim. *Id.* at 15-16. This argument is illogical. If petitioners put forth a theory of causation, respondent cannot possibly negate that theory by showing an alternative sole substantial cause exists. Simultaneously, without proving said sole substantial cause (which petitioners have already

asserted to be legally impossible if petitioners have set forth a causal theory, no matter how improbable), petitioners should be entitled to vaccine compensation. The petitioner has misinterpreted the law.

According to the Federal Circuit, “the standards that apply to a petitioner’s proof of actual causation in fact in off-table cases should be the same as those that apply to the government’s proof of alternative actual causation in fact.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994). Respondent set forth an alternative causal theory for H.E.F.’s Dravet syndrome—the SCN1A genetic mutation, which H.E.F. inherited from her mother. Petitioners argue that the SCN1A mutation could not have caused the H.E.F.’s Dravet syndrome, because Ms. Faoro was asymptomatic, and inherited genetic mutations typically result in a lesser form of the disease than was exhibited in the parent from whom it was inherited. Mem. Supp. MFR at 13. The Chief Special Master disagreed with this assertion, finding that Dr. Raymond’s testimony regarding mosaicism was persuasive. Mosaicism explains why Ms. Faoro was asymptomatic, but H.E.F. developed Dravet syndrome. As such, the Chief Special Master applied the proper legal standard in determining that the SCN1A mutation was a causal factor unrelated to H.E.F.’s vaccination, and petitioners’ burden of proof for *Althen* prong one was not increased.

## **B. The *Loving* Test**

In addition to asserting that H.E.F.’s vaccines caused her seizure disorder, petitioners also argue that the vaccines significantly aggravated her Dravet syndrome. This is primarily premised on the fact that H.E.F. inherited her SCN1A mutation from her mother, who is asymptomatic. Mem. Supp. MFR at 16-17. The first step of the *Loving* test is to determine “[H.E.F.’s] condition prior to administration of the vaccine.” Dec. at 31 (quoting *Loving*, 86 Fed. Cl. at 144). Petitioners take issue with Chief Special Master Dorsey’s findings that H.E.F. was born with a SCN1A mutation and that her mutation is of an ilk typically associated with severe epilepsy and Dravet syndrome. Petitioners argue that “the proper review of an aggravation claim is to presume that the pre-existing condition is benign and then analyze whether the introduction of the vaccine alters that condition.” Mem. Supp. MFR at 18. That is not the *Loving* test.

The fact that H.E.F. was born with a mutation at SCN1A is not up for debate. She has been genetically tested, and both parties agree that this genetic mutation was not caused by the vaccine. Dec. at 27. Dr. Kinsbourne was unable to provide any reliable medical literature or testimony in support of his theory that, but for the vaccine, H.E.F.’s Dravet syndrome would have developed differently. *Id.* at 28. Dr. Kinsbourne has no experience treating children with Dravet syndrome, and thus, no firsthand experience or knowledge of the progression of the disease. *Id.* Respondent’s experts, however, both have extensive experience working with children with Dravet syndrome, and both experts testified that H.E.F.’s Dravet syndrome was and continues to be consistent with the expected clinical course of Dravet syndrome. *Id.*

Additionally, the Chief Special Master based her decision on four previous SCN1A cases. In each of those four cases, the special master found that the SCN1A mutation was the sole cause of Dravet syndrome, and, therefore, a factor unrelated to the vaccine and actual cause of the

injury. *See Stone v. Sec’y of Health & Human Servs.*, No. 04-1041V, 2010 WL 1848220 (Fed. Cl. Spec. Mstr. Apr. 15, 2010); *Hammitt v. Sec’y of Health & Human Servs.*, No. 07-170V, 2011 WL 1135878 (Fed. Cl. Spec. Mstr. Mar. 4, 2011); *Snyder v. Sec’y of Health & Human Servs.*, No. 07-59V, 2011 WL 3022544 (Fed. Cl. Spec. Mstr. May 27, 2011); *Harris v. Sec’y of Health & Human Servs.*, No. 07-60V, 2011 WL 2446321 (Fed. Cl. Spec. Mstr. May 27, 2011). All four of these cases were appealed to the Federal Circuit, and all four of these cases were affirmed. *See Snyder v. Sec’y of Health & Human Servs.*, 553 Fed.Appx. 994 (Fed. Cir. 2014). Chief Special Master Dorsey noted that “[c]ompensation has been denied in similar cases based upon a finding that the SCN1A mutation was a ‘factor unrelated to the administration of the vaccine’ and the agent solely responsible for causing Dravet syndrome in a child.” Dec. at 35 (citing *Deribeaux v. Sec’y of Health & Human Servs.*, 717 F.3d 1363 (Fed. Cir. 2013)). It is clear to this court that the Chief Special Master’s application of step one of the *Loving* test did not increase petitioners’ burden of proof.

### III. CONCLUSION

This court finds that petitioners have not met their burden of proof in alleging that H.E.F.’s vaccinations led to or significantly aggravated her seizures and Dravet syndrome. For the foregoing reasons, the court **DENIES** petitioner’s motion for review.<sup>18</sup>

**IT IS SO ORDERED.**

s/ *Loren A. Smith*

Loren A. Smith,  
Senior Judge

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<sup>18</sup> This opinion shall be unsealed, as issued, after April 25, 2016, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.